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PRINCIPAL INVESTIGATOR: Julian M. Goldman, MD

CONTRACTING ORGANIZATION: Massachusetts General Hospital, Boston, MA 02114

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14. ABSTRACT
Partial support was requested from TATRC, with joint funding from NSF, for a joint workshop to bring together the synergistic efforts and communities of the High Confidence Medical Devices, Software, and Systems (HCMDSS) program and the Medical Device "Plug-and-Play" (MD PnP) Interoperability program to provide a forum to exchange and learn from new research and development results by these groups. The three-day workshop drew 145 participants from academia, industry, government, and health care, including researchers, developers, regulators, users, and manufacturers of medical devices, as well as interested government agencies. The opening keynote address was given by Dr. Robert Kolodner, the National Coordinator for Health IT, and the program included refereed papers, panels on the Clinical Need and on Government Perspectives on Interoperability, a session of posters and scientific demonstrations in the MD PnP Lab, and breakout sessions on selected topics. The workshop proceedings were published by the IEEE Computer Society. Results included broadened perspectives and an expanded network of collaborators and stakeholders for both programs, presentations of meeting results in multiple venues, and new collaborations, as well as streaming video of all talks on the web.

15. SUBJECT TERMS
Medical device, interoperability, high confidence systems, embedded systems, patient safety, device control, health care

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Report on HCMDSS / MD PnP Joint Workshop Held on June 25-27, 2007
USAMRAA Award Number W81XWH-07-1-0512
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Introduction

Medical devices are essential for the practice of modern medicine. However, unlike the inter-connected "plug-and-play" world of modern computers and consumer electronics, most medical devices are designed to operate independently, and do not employ open networking standards for data communication or for device control. Integrating medical devices into patient-centric networks can provide comprehensive data for the EMR and support advances in patient safety and improved workflow, such as automated system readiness assessment, physiologic closed-loop control of medication, fluid delivery, and ventilation, safety interlocks, monitoring of device activity, and decision support. Such improvements should reduce medical errors and healthcare costs to the benefit of patients throughout the continuum of care, from the home to transport to clinical areas as diverse as the OR, ICU, and general hospital ward, as well as on the battlefield and in mobile care units used by the military and in disaster recovery.

Despite the importance of applying systems engineering solutions such as interoperability to healthcare, medical device vendors have not adopted cross-vendor standards-based interoperability for medical system integration. When device integration is required, customized device communication interfaces must be developed at increased cost. The rapidly increasing use of software to control medical devices makes the development and production of medical device software and systems a crucial issue, both for the U.S. economy and to assure safe advances in healthcare delivery. There is strong interest in advancing research and development to improve the design, certification, and operation (by both healthcare practitioners and consumers) of medical device software and systems to result in better and more cost-effective medical care.

Synergies between the goals of existing programs on HCMDSS (High Confidence Medical Devices, Software, and Systems) and Medical Device Plug-and-Play (MD PnP) Interoperability became apparent early in 2005, grew as a result of collaborative work during 2005-2007, and led to the first Joint Workshop on HCMDSS and MD PnP Interoperability, which was held in Cambridge, MA, on June 25-27, 2007, and was jointly funded by TATRC and NSF. The HCMDSS / MD PnP Joint Workshop on "Improving Patient Safety through Medical Device Interoperability and Highly Reliable Software" was intended to bring together a diverse group of clinical and technological experts who are addressing these issues, and to accelerate the development of interoperability solutions through the sharing of research results and the formation of future collaborations, to the benefit of patients everywhere.

Body of Report

The Medical Device Plug-and-Play (MD PnP) Interoperability program was established in 2004 to lead the evaluation and adoption of open standards and technology for medical device interoperability to support clinical innovation. Led by Julian M. Goldman, MD, the program is affiliated with Massachusetts General Hospital (MGH), CIMIT (Center for Integration of Medicine and Innovative Technology), and Partners HealthCare Information Systems, with additional support from TATRC (U.S. Army Telemedicine & Advanced Technology Research Center). Having evolved from the OR of the Future program at MGH, the MD PnP program remains clinically grounded. We have convened diverse stakeholders (clinicians, biomedical and clinical engineers, regulatory agencies, medical device vendors, standards experts) to learn from past efforts, to harmonize with current synergistic programs, and to elicit clinical scenarios. Since the program's inception, more than 600 clinical and engineering experts, and representatives of more than 85 institutions that share a vision of medical device interoperability have participated in ongoing convening activities. Our geographically dispersed, multidisciplinary, multi-

institutional team of collaborators has included participants from: Kaiser Permanente, Draper Laboratory, FDA, University of Pennsylvania Dept of Computer and Information Science, Draeger Medical Systems, LiveData Inc., Mitre Corporation, DocBox Inc., University of New Hampshire, IXXAT, NIST, NSF, Geisinger Health System, as well as the Partners HealthCare System community (MGH Anesthesia, Biomedical Engineering at MGH and Brigham & Women's Hospital, and Partners HealthCare Information Systems).

Also in 2004, several Federal agencies recognized the challenges of the rapidly increasing use of software to control medical devices, making the development and production of embedded medical device software and systems critical to both the U.S. economy and the assurance of safe advances in healthcare delivery. Led by NSF, these agencies convened representatives from academia, government, and industry to discuss the research required to improve the design, certification, and operation of medical device software and systems that will result in better, safer, and more cost-effective medical care. The first HCMDSS workshop, held in June 2005, was organized by Prof. Insup Lee (Dept of Computer & Information Science) and Prof. George Pappas (Department of Electrical & Systems Engineering), University of Pennsylvania, with NSF funding. Participants included researchers, developers, certifiers, and users, who helped identify emerging systems and assurance needs. The workshop resulted in a comprehensive research needs report with prioritized recommendations and a roadmap for how these priorities should be addressed over an identified timeframe.

The synergies between HCMDSS and MD PnP goals became apparent early in 2005 – Dr. Goldman and Prof. Lee presented at each other's workshops that June – and have grown as a result of collaborative work during 2005-2007, leading to this joint workshop to continue the momentum and to provide a forum to exchange and learn from new research and development results by the emerging community of researchers, developers, regulators, users, and manufacturers.

The purpose of the joint workshop on HCMDSS and MD PnP Interoperability was to provide a working forum for medical device specialists, including researchers, developers, and caregivers, from clinical environments, industry, research laboratories, academia, and government with the goal of advancing science, technology, and practice to address crucial software and systems issues and challenges in the design, manufacture, certification, use, and interoperability of medical devices.

The June 25-27, 2007 Joint Workshop on HCMDSS and MD PnP Interoperability, jointly funded by NSF and TATRC, was organized by the MD PnP program (Julian M. Goldman, MD, and Susan Whitehead, CIMIT) with the University of Pennsylvania Dept of Computer Science (Insup Lee, PhD, and Oleg Sokolsky, PhD). The workshop, chaired by Dr. Goldman and Prof. Lee, brought together two highly synergistic program communities and drew 145 participants from academia, industry, government, and health care. The opening keynote address was given by Dr. Robert Kolodner, the National Coordinator for Health IT, and the second day opened with a keynote talk by Dr. John Rushby of SRI International. The program included refereed papers, panels on the Clinical Need and on Government Perspectives on Interoperability, a session of posters and scientific demonstrations in the MD PnP Lab, and breakout sessions on selected topics. In addition, the attendees participated in the weekly CIMIT Forum, dedicated that week to HCMDSS / MD PnP topics, with three invited speakers. This was the fourth MD PnP program conference in three years, and the second HCMDSS workshop in two years.

Program. Program planning was done by the workshop organizers (Goldman, Lee, Whitehead, and Sokolsky), with valuable input from Helen Gill and Sylvia Spengler (NSF), Ronald Marchessault (TATRC), and Vish Sankaran (Office of the National Coordinator for Health IT). The three-day workshop program included research presentations that were either invited by the workshop organizers or submitted in response to a call for papers. Refereed papers were on research and development of many aspects of high integrity medical device software and

systems that are essential to support networking medical device systems to improve safety and efficiency in health care. Other talks were invited to provide clinical perspectives and to describe work being done on methodologies for eliciting clinical requirements for medical device interoperability. The presentations were organized into moderated technical sessions on Interoperability Challenges, High Confidence Software, Sensor Networks, and Interoperability Solutions.

Breakdown of workshop presentations

- 2 keynote talks
- 13 refereed full papers
- 21 extended abstracts
- 10 invited talks (6 during the workshop, 3 at the CIMIT Forum, one at dinner)
- 12 panel talks
- 21 posters
- 8 technical or scientific demonstrations

A panel on The Clinical Need was organized to convey the perspectives of clinicians and others in healthcare delivery systems on the need for medical device interoperability. The discussion period afterwards and other networking opportunities during the workshop provided a unique opportunity for the HCMDSS computer scientists to interact with the users of the high confidence systems they are designing.

A panel on Government Perspectives on Interoperability gave participants a chance to hear from representatives of government agencies that are interested in advancing the work of HCMDSS and MD PnP, including NSF, TATRC, FDA, NITRD, NIST, and NIH (NIBIB). This was the first time all of these agencies had shared a public platform on this topic.

In addition to the refereed papers and panel discussions, there were 21 five-minute talks on relevant work in progress, which were then presented on the second afternoon in a poster session and a set of demonstrations of HCMDSS / MD PnP technologies by both universities and companies.

The CIMIT MD PnP Lab hosted these scientific exhibits and demonstrations in our collaborative space in Cambridge, MA. This afternoon poster-demo session was one of the liveliest of the entire workshop, and gave participants a valuable interactive opportunity to share their work. There were also several other opportunities for networking among the participants during the course of the conference.

The CIMIT Forum, held following the poster-demo session, provided workshop participants an opportunity to join with members of the CIMIT community to hear presentations by invited speakers from the Continua Health Alliance, Kaiser Permanente, and the IHE (Integrating the Healthcare Enterprise), a standards organization sponsored by the Healthcare Information & Management Systems Society (HIMSS).

On the last day of the workshop, breakout sessions were held over lunch on the following medical device topics: adverse event recording, human/computer device interactions, validation and certification, MD PnP ontology, life cycle management of interoperable systems and contract language for interoperability, and medical sensor networks. The results of these groups were presented back as a “call to action” for work going forward. Throughout the workshop, Tim Gee tracked its progress through real-time reporting on his Medical Connectivity blog site (http://medicalconnectivity.com), and during the wrap-up of the meeting he shared his “view from the blogosphere”.

Selection of Papers. A competitive Call for Papers resulted in 30 submitted papers, which were a mix of technical papers and position papers or summaries of work-in-progress. A multi-

institutional program committee of 20 content experts reviewed the submissions, and accepted 13 papers for full presentation (20 minutes) at the workshop. The remaining authors were asked to submit an extended abstract on their work, to be presented briefly (5 minutes) and shown in a poster session or demonstration. Three papers were withdrawn at that point.

Papers were solicited on topics that covered all aspects of HCMDSS and MD PnP, including but not limited to:

- Foundations for Integration of Medical Device Systems/Models: Component-based technologies for accelerated design and verifiable system integration, Systems of systems, MD PnP (Plug-and-Play) to support interoperability of heterogeneous systems
- Enabling Technologies for Future Medical Devices: Implantable regulatory devices, networked biosensors, telesurgery, robotic surgery, physiologic signal QoS (Quality of Service)
- Distributed Control & Sensing of Networked Medical Device Systems: Robust, verifiable, fault-tolerant control of uncertain, multi-modal systems
- Medical Device Plug-and-Play Ecosystem: Requirements for supporting interoperability in the clinical environment, including "black box'" data recording, device authorization, and data security.
- Embedded, Real-Time, Networked System Infrastructures for HCMDSS: Architecture, platform, middleware, resource management, QoS in HCMDSS, Dynamic interoperation in HCMDSS, including MD PnP (Plug-and-Play) operation
- High Confidence Medical Device Software Development & Assurance: Care-giver requirements solicitation and capture, design and implementation, V&V (Verification and Validation), Heterogeneity in environment, architecture, platforms in medical devices
- Medical Practice-driven Models and Requirements: User-centric design, risk understanding, and use/misuse modeling in medical practice, management of failures in a clinical environment, modeling of operational scenarios, including medical devices, care-givers, patients
- Certification of HCMDSS and MD PnP: Quantifiable incremental certification of HCMDSS and MD PnP interoperability, role of design tools and COTS, approval of non-deterministic and self-adaptive medical device systems
- Life Cycle Management of Networked Devices and HCMDSS: Maintainability issues and methods, monitoring of networked devices, bringing new devices onto the network, implications for legacy systems

An additional Call for Extended Abstracts of 750 words was made to elicit papers to fill some gaps in the coverage of key topics. We sought extended abstracts that reflected work in progress, discussed challenging open problems, and explored collaborations with other related areas. We also solicited the submission of abstracts for demonstrations. Twelve additional abstracts were submitted for posters and demos.

Participants. The demographics of the 145 meeting attendees, who represented 80 organizations, included the following:

Organization Sector

- Academic 37
  - Students 22
- Healthcare Institutions:
  - Clinical 8
  - Biomedical Engineering 4
  - Healthcare IT 3
  - Delivery Systems 1
  - CIMIT 7

- Government 17
- Industry 36
- Not-for-profit 6
- Consultant 2
- Healthcare media 2

Organization Country

- U.S. 135
- International 10
  - Germany 4
  - Taiwan 3
  - Canada 2
  - Italy 1

Prior Program Interest

- MD PnP 75
- HCMDSS 60

Participant Evaluations. On the final day of the workshop, participants were given a meeting evaluation form, and we received back 22 completed forms from the 80 attendees remaining at that time (28% return rate). Responses to the three evaluation questions can be summarized as follows:

Which aspects of the conference did you enjoy the most?

- Diversity of participation (especially clinical and government) and of talks
- Networking with other participants
- Well organized

Which aspects of the conference did you like the least?

- Not keeping speakers to time limits and meeting to schedule, leaving inadequate time for Q&A, especially with panels
- Timetable too tight to allow for more interactions among participants
- Mix of HCMDSS and MD PnP topics was well-received by some, confusing to others, left some feeling their area didn't get enough attention

Was there anything that you felt was missing?

- Success stories
- More small group opportunities, interactive breakouts
- In-depth discussion of difficult, complex topics

Twenty of the respondents said they would participate in another such conference.

Outputs. Meeting registrants received a notebook including a welcome letter from the workshop co-chairs, the agenda, the roster of registered attendees by name and by organization, copies of the papers and abstracts, and articles on the MD PnP program and HCMDSS.

Talks given at the workshop were videotaped and subsequently made available as streaming video, with links on the conference web site (http://rtg.cis.upenn.edu/hcmdss07), as well as on the MD PnP (www.mdpnp.org) and CIMIT web sites (www.cimit.org). There have been over 3900 hits on these pages since they became available in August 2007. The three talks most frequently accessed are Dr. Sandy Weininger's talk on an FDA view of interoperability and clinical requirements, the talk by Tracy Rausch and Jennifer Jackson on using clinical workflows to improve device/system development, and Dr. Steven Dain's talk on the historical clinical perspective on interoperability, part of the panel on The Clinical Need.

The Proceedings of the workshop (submitted papers and abstracts) were published in January 2008 by the IEEE Computer Society. Copies of the Proceedings were distributed to meeting attendees and to the program officers at the sponsoring agencies (NSF and TATRC).

The letter of support from the U.S. FDA, which was read at the workshop, is available on the MD PnP web site and was published in the workshop Proceedings.

Workshop attendees from the medical media published brief articles about the meeting in the online versions of the *Boston Globe* and the *Patient Safety & Quality Healthcare* journal.

Conference Highlights and Key Research Accomplishments:

- Broadening of the stakeholder community for both the MD PnP program and the HCMDSS program, while preserving existing interest
- New contacts and potential collaborators for each program, broadening the potential impact of current research
- Expanded perspectives for each program: the MD PnP group learned more about the implementation side of interoperable systems, and the HCMDSS group was exposed to clinicians and biomedical engineers who live day-to-day with medical devices
- Discussion of a framework for funding these program efforts going forward, and program exposure to a spectrum of government agencies who want to help, convened publicly for the first time as a group on this topic

As with earlier MD PnP and HCMDSS conferences, this workshop has led to collaborative activities that have continued to broaden support for the vision and goals of both programs. These have included new collaborations to seek funding for projects to investigate networked medical devices as safety-critical systems.

The web of collaborations for the MD PnP program began with the TATRC-sponsored May 2004 symposium and has continued to grow as a result of subsequent conferences and activities, including this workshop. These collaborations include relationships with federal agencies; clinical, engineering, and IT societies; clinicians in the USA, Europe, Japan, and now Taiwan; integrated health delivery networks; and now, academic computing groups.

Reportable Outcomes

Meetings:

- Dec 2007 Workshop on Software and Systems for Medical Devices and Services
- May 2008 GPA working group at GSA Certification Workshop (30 participants)

MD PnP Presentations:

- June 25 2007 at the Joint Workshop on High Confidence Medical Devices, Software, & Systems (HCMDSS) / Medical Device Plug-and-Play (MD PnP) Interoperability in Cambridge, MA
- June 26 2007 at the CIMIT Forum on Medical Device Interoperability in Cambridge, MA
- June 30 2007 at the Computer-Assisted Radiology & Surgery (CARS) conference in Berlin, Germany
- August 15 2007 at ATACCC in St. Pete, FL
- August 27 2007 at the New England Medical Center Grand Rounds in Boston
- August 30 2007 at the MGH Anesthesia Grand Rounds in Boston
- October 1 2007 at AdvaMed in Washington DC

- October 2 2007 to program leaders at NIBIB in Rockville, MD
- October 3 2007 at the Global Harmonization Task Force conference in Washington DC
- October 13 2007 at the 2007 Annual Meeting of the American Society of Anesthesiologists (ASA) in San Francisco, CA
- October 29 2007 at National Taiwan University Hospital (an invitation that resulted from our June HCMDSS / MD PnP conference)
- November 13 2007 at the 2007 CIMIT Innovation Congress in Boston, MA
- November 29 2007 at the National OR of the Future Conference in Orlando, FL
- December 9 2007 at the Anesthesiology Patient Safety Foundation (APSF) Committee on Technology meeting in New York, NY
- January 17-18 2008 at the Society for Technology in Anesthesia annual meeting, San Diego, CA
- January 25 2008 at the ISO Technical Committee 121, Subcommittee 2 meeting, London, ENG on "Airway Laser Safety"
- February 5 2008 at the Veterans Affairs Enterprise Architecture Open Management Meeting, Grand Junction, CO
- February 13 2008 at CIMIT for a visiting Hospira team from the Global Devices group
- March 4 2008 at the World Congress of Anesthesia in South Africa
- March 27 2008 at National Forum on the Future of the Defense Health Information System, Washington DC
- April 5 2008 at "TATRC Day" at the American Telemedicine Association in Seattle, WA
- April 25 2008 at the Tokyo Women's Medical University, Tokyo, Japan
- May 20 2008 at the GSA Collaborative Expedition Workshop on "Potentials and Realities of Certification in Light of Open Technology Development", Washington, DC

HCMDSS Presentations:

- June 25 2007 at the Joint Workshop on High Confidence Medical Devices, Software, & Systems (HCMDSS) / Medical Device Plug-and-Play (MD PnP) Interoperability in Cambridge, MA
- September 6 2007 at the NSF Symposium on Cyber-Enabled Discovery and Innovation, Rensselaer Polytechnic Institute (RPI), Troy, NY
- December 11 2007 at the Software Certification Consortium organizational meeting in Minneapolis, MN
- May 15 2008 at the 10th Software Design for Medical Devices Conference in Philadelphia, PA

Web Sites:

- http://rtg.cis.upenn.edu/hcmdss07 – the official workshop site
- www.mdpnp.org – the web site of the MD PnP program; contains pointers to workshop summary information and to the streaming video of the workshop talks
- www.cimit.org – the web site of CIMIT, the Center for the Integration of Medicine & Innovative Technology; contains the streaming video of the workshop talks

Manuscripts/Publications:

- Cooney, Elizabeth, "Getting medical devices to talk to each other," *White Coat Notes*, in the online *Boston Globe*, June 25, 2007.
- Carr, Susan, "Plug and play for patient safety," editorial in *Patient Safety & Quality Healthcare* online, July-Aug 2007.
- Goldman JM, Lee I, *et al*, *Proceedings of the Joint Workshop on High-Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play*

Interoperability (HCMDSS / MD PnP 2007), *Cambridge, MA, June 25-27, 2007*, IEEE Computer Society Press, January 2008.

Funding Applications resulting from Conference:

- Submitted to NSF: $400K MGH subcontract (4 years) as part of proposal by University of Illinois at Urbana-Champaign
- Submitted to NSF: $400K MGH subcontract (4 years) as part of proposal by University of Pennsylvania

Conclusions

The convening of this group of thought leaders in the areas of medical device interoperability and high confidence embedded systems provided a unique opportunity for the kind of intellectual exchange needed to advance the field. As with previous workshops for HCMDSS and for the MD PnP program, this one has resulted in extensive networking and collaborative activities that have facilitated parallel efforts in technology, methodology, and standards development. Clinical participants were exposed, many for the first time, to computer systems engineers and scientists who can build the kinds of systems they need. Academic computer scientists were able to interact, many for the first time, with clinicians and biomedical engineers who are the hands-on users of medical device systems.

The HCMDSS / MD PnP joint conference addressed the issues surrounding medical device interoperability and how to implement such safety-critical systems, in order to improve patient safety and healthcare efficiency – this has broad implications for the future of health care, with a potential impact far beyond the science and engineering communities.

References

- Goldman JM, Jackson JL, Whitehead SF, Rausch TL, Weininger S, "The Medical Device 'Plug-and-Play' (MD PnP) Interoperability Program," part of Schrenker RA, "Software Engineering for Future Healthcare and Clinical Systems," *IEEE Computer,* April 2006.
- Goldman JM, "Medical Device Connectivity for Improving Safety and Efficiency," *American Society of Anesthesiology Newsletter* 70:5, May 2006. http://www.asahq.org/Newsletters/2006/05-06/goldman05_06.html
- Goldman JM, Whitehead S, Weininger S, "Eliciting Clinical Requirements for the Medical Device Plug-and-Play (MD PnP) Interoperability Program," *Anesthesia & Analgesia* 2006;102:S1-54.
- Goldman JM, Lee I, *et al*, *Proceedings of the Joint Workshop on High-Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (HCMDSS / MD PnP 2007)*, *Cambridge, MA, June 25-27, 2007*, IEEE Computer Society Press.
- Whitehead SF, Goldman JM, "Getting Connected for Patient Safety," *Patient Safety & Quality Healthcare* 5:1, Jan-Feb 2008.

Appendices

HCMDSS / MD PnP Joint Workshop Program
HCMDSS / MD PnP Joint Workshop Roster by Name
HCMDSS / MD PnP Joint Workshop Roster by Institution/Organization
U.S. FDA Position Letter
Title Page of Workshop Proceedings
White Coat article
PSQH editorial

University of Pennsylvania
Department of Computer
& Information Science

MD PnP™
Getting connected for patient safety™

Improving Patient Safety through Medical Device Interoperability and High Confidence Software

Joint Workshop on
High Confidence Medical Devices, Software, and Systems (HCMDSS) and Medical Device Plug-and-Play (MD PnP) Interoperability

June 25-27, 2007
Cambridge, MA

With support from: TATRC (U.S. Army Telemedicine & Advanced Technology Research Center), NSF (National Science Foundation), AHRQ (Agency for Healthcare Research & Quality), CIMIT (Center for Integration of Medicine & Innovative Technology), Massachusetts General Hospital and the University of Pennsylvania

Hyatt Regency Cambridge, 575 Memorial Drive, Cambridge, MA

Monday, June 25

7:30 – 8:30am	Registration / Continental Breakfast

8:30 – 8:55am	Welcome from Workshop Co-Chairs and Conference Overview *Insup Lee, PhD, University of Pennsylvania* *Julian M Goldman, MD, Massachusetts General Hospital / CIMIT*
8:55 – 9:00am	Welcome from CIMIT *John A Parrish, MD, Director*
9:00 – 10:00am	Keynote Address: *Robert M Kolodner, MD, National Coordinator for Health IT*
10:00 – 10:20am	Break

Monday, June 25 (continued)

10:20 – 12:00 noon **Panel on The Clinical Need**
Moderator and Introduction to Panel: Julian M Goldman, MD
Jeffrey Cooper, PhD, Anesthesia Patient Safety Foundation, MGH
Sandy Weininger, PhD, Food & Drug Administration
Jennifer Jackson, MBA, CCE, Brigham & Women's Hospital
James Philip, MEE, MD, Brigham & Women's Hospital
Steven Dain, MD, University of Western Ontario
James Fackler, MD, Johns Hopkins Medical Center
Panel Discussion

12:00 – 1:00pm Lunch Buffet and Extended Abstract Talks (starting at 12:30)

1:00 – 3:00pm **Technical Session 1:** Interoperability Challenges
Introduction to Session: Glenn Himes, Mitre Corporation

Medical Device Interoperability: Assessing the Environment
Kathy Lesh, Sandy Weininger, Julian Goldman, Bob Wilson, Glenn Himes
See roster for institutional affiliations.

Moving Toward Semantic Interoperability of Medical Devices
John Garguilo, Sandra Martinez, Richard Rivello, Maria Cherkaoui
NIST – National Institute of Standards & Technology

Clinical Requirements Methodology: Incorporating Clinical Workflows to Improve Device/System Development
Invited Speakers: Jennifer Jackson, Brigham & Women's Hospital, Tracy Rausch, DocBox Inc. (formerly at Kaiser Permanente)

Clinical Requirements Methodology: Ensuring Sufficient Breadth in Use Case Development – How Should Non-Functional Requirements be Elicited and Represented?
Invited Speaker: Richard Schrenker, Massachusetts General Hospital

Challenges for the Large Integrated Healthcare Delivery System
Invited Speaker: Michael Robkin, Kaiser Permanente

Session Recap & Discussion: Glenn Himes

3:00 – 3:30pm Break

3:30 – 5:00pm **Technical Session 2:** High Confidence Medical Device Software
Introduction to Session: Helen Gill, NSF

Formal Methods Based Development of a PCA Infusion Pump Reference Model: Generic Infusion Pump (GIP) Project
David Arney, Raoul Jetley, Paul Jones, Insup Lee, Oleg Sokolsky
See roster for institutional affiliations.

Monday, June 25 (continued)

Point-of-Care Support for Error-Free Medication Process
JWS Liu, CS Shih, PH Tsai, HC Yeh, PC Hsiu, CY Yu, WH Chang
See roster for institutional affiliations.

A Survey of Software Engineering Techniques in Medical Device Development
Raimund L. Feldmann, Forrest Shull, Christian Denger, Martin Höst, Christin Lindholm
See roster for institutional affiliations.

5:00 – 6:00pm Abstract Talks

6:00 – 7:00pm Reception and
7:00 – 9:00pm Dinner – at Hyatt Regency, Charles View Ballroom
Dinner Speaker: Nat Sims, MD, Physician Advisor, Partners HealthCare Biomedical Engineering at Massachusetts General Hospital
Introduced by *Warren M. Zapol, MD, Reginald Jenny Professor, and Chairman, Department of Anesthesia & Critical Care, Massachusetts General Hospital*

Tuesday, June 26

7:30 – 8:30am Continental Breakfast

8:30 – 8:45am Introduction to **Day #2**: *Insup Lee*

8:45 – 9:45am Keynote Address:
John Rushby, PhD, Program Director for Formal Methods & Dependable Systems, SRI International

9:45 – 10:00am Break

10:00 – 12:00 noon **Technical Session 3:** Sensor Networks
Introduction to Session: Azer Bestavros, Boston University

User Access of Public Shared Devices in Pervasive Computing Environments
David Jea, Ian Yap, Mani Srivastava
UCLA

PAS: A Wireless-Enabled, Sensor-Integrated Personal Assistance System for Independent and Assisted Living
Jennifer Hou, Qixin Wang, Linda Ball, Stanley Birge, Marco Caccamo, Chin-Fei Cheah, Eric Gilbert, Carl Gunter, Elsa Gunter, Chang-Gun Lee, Karrie Karahalios, Min-Young Nam, Narasimhan Nitya, Chaudhri Rohit, Lui Sha, Wook Shin, Yang Yu, Zheng Zeng
See roster for institutional affiliations.

Tuesday, June 26 (continued)

A Novel Method and Testbed for Sensor Management and Patient Diagnosis
Winston Wu, Maxim Batalin, Alex Bui, Majid Sarrafzadeh, William Kaiser
UCLA

Platform Design for Healthcare Monitoring Applications
Roozbeh Jafari, Ruzena Bajcsy, Steven Glaser, Bruce Gnade, Marco Sgroi
See roster for institutional affiliations.

Session Recap: Azer Bestavros

12:00 – 1:00pm — Lunch Buffet and Extended Abstract Talks (starting at 12:30)

1:00 – 1:20pm — Overview of Afternoon Sessions
Julian Goldman

1:20 – 1:45pm — **Transport to CIMIT (Cambridge), 65 Landsdowne Street, Cambridge**

1:45 – 3:50pm — Demos and Posters at MD PnP Lab, CIMIT (Cambridge)
Various Presenters

3:50 – 4:00pm — Move into CIMIT Forum (beverages and snacks provided)
65 Landsdowne Street, Room 103 (same building)

4:00 – 6:00pm — **CIMIT Forum**
Moderated by Julian M. Goldman, MD
Accelerating Interoperability:
Dave Whitlinger, Director, Healthcare Device Standards, Intel Corporation
Zachary Zimmerman, MD/MS, Chair of Chiefs of Anesthesia, Kaiser Permanente
Ray Zambuto, IHE-USA
Panel: *Jeff Robbins, LiveData Inc., Carl Wallroth, Drager Medical, Dave Whitlinger, Zachary Zimmerman, Ray Zambuto*

6:30 – 8:30pm — **Reception – MIT Museum**
Mass Ave, Cambridge (5-minute walk from 65 Landsdowne St)

Wednesday, June 27

7:30 – 8:30am	Continental Breakfast

8:30 – 8:45am	Introduction to **Day #3**: *Julian Goldman*
8:45 – 9:45am	**Government Perspectives** *Invited Speakers: Sally Howe, National Coordination Office for Networking & Information Technology Research & Development (NITRD)* *Sylvia Spengler, NSF, Michael Fitzmaurice, AHRQ* *Introduction to Panel: Vish Sankaran, Federal Health Architecture, Office of the National Coordinator for HIT*
9:45 – 10:00am	Break
10:00 – 11:30am	**Panel on Government Perspectives on Medical Device Interoperability** *Moderator: Vish Sankaran* *NIST: John J Garguilo* *FDA: Sandy Weininger* *TATRC: Ronald Marchessault* *NSF: Scott Midkiff* *NIH: Zohara Cohen* *Panel Discussion and Q&A*

11:30 – 12:30pm	Networking Lunch Buffet

12:30 – 2:45pm	**Technical Session 4:** Interoperability Solutions *Introduction to Session: Jeff Robbins, LiveData Inc.* MD-Adapt: A Proposed Architecture for Open-Source Medical Device Interoperability Interoperable Medical Devices Due to Standardized CANopen Interfaces *Reiner Zitzmann, Thilo Schumann* *CAN in Automation* Building Reliable MD PnP Systems *Mu Sun, Qixin Wang, Lui Sha* *University of Illinois, Urbana-Champaign* Agent-Based Plug-and-Play Integration of Role-Enabled Medical Devices *Giacomo Cabri, Francesco De Mola, Letizia Leonardi* *University of Modena, ITALY* Plug-and-Play and Network-Capable Medical Instrumentation and Database with a Complete Healthcare Technology Suite: MediCAN *Paul McKneely, Frank Chapman, Deniz Gurkan* *MediCAN Systems, University of Houston*

Wednesday, June 27 (continued)

Session Recap: Jeff Robbins

2:45 – 3:00pm	Break
3:00 – 3:45pm	**Breakouts for Working Groups** (brainstorming key issues) *Facilitators TBD* • *Adverse Event Reporting* • *Human Computer Interface* • *Validation and Certification* • *MD PnP Ontology* • *Life-Cycle Management of Interoperable Medical Device Systems* • *Interoperability Requirements in Contract Language*
3:45 – 4:15pm	Working Groups report back
4:15 – 4:30pm	*Commentary: View from the Blogosphere* *Tim Gee, www.medicalconnectivity.com*
4:30 – 5:00pm	Workshop Wrap-up: Lessons Learned and Next Steps *Insup Lee and Julian M. Goldman, MD*
5:00pm	**Adjourn**

Please Note: Full institutional affiliations by individual will be available in the published Proceedings of the meeting.

HCMDSS / MD PnP Workshop
Final Attendees List

First Name	Last Name	Organization / Company
Marwan	Abdeen	McMaster University
Oscar	Almeida	Texas A&M University
David	Arney	University of Pennsylvania
Maxim	Batalin	UCLA
Trudy	Bell	NCO NITRD
Azer	Bestavros	Boston University
Jim	Biondi	Cardiopulmonary Corp.
Steven	Boutrus	CIMIT
David	Broniatowski	MIT
Darin	Buxbaum	Stanford University
Susan	Carr	Patient Safety & Quality Healthcare
Orieta	Celiku	Carnegie Mellon University
Yung-Chun	Chen	University of Washington
Duncan	Clarke	Fremont Associates, LLC
Zohara	Cohen	NIBIB/NIH
Elizabeth	Cooney	The Boston Globe
Jeffrey	Cooper	Partners HealthCare Biomedical Engineering
Philippe-Antoine	Cortes	University of Pennsylvania
Janice	Crosby	CIMIT
Steven	Dain	University of Western Ontario
Francesco	De Mola	University of Modena and Reggio Emilia
Ann	Demaree	CapsuleTech, Inc.
Robert	Dingwell	The MITRE Corporation
Steve	Dixon	Hill-Rom
Amy	Droitcour	ALZA
Scott	Eaton	Datascope Corp
Ryan	Eavey	Stryker
Jill	Egeth	The MITRE Corporation
Javier	Espina	Philips
Jim	Fackler	Johns Hopkins University
Jeanne	Fandozzi	The MITRE Corporation
Raimund	Feldmann	Fraunhofer Center, Maryland
Jim	Fidacaro	Datascope Corp.
Penny	Ford-Carleton	CIMIT
Gordon	Fowler	DocBox Inc
John	Garguilo	NIST
David	Garlan	Carnegie Mellon University
Mark	Gaynor	Boston University
Tim	Gee	Medical Connectivity
Christopher	Gill	Washington University
Gigi	Gilman	Partners Healthcare
Julian	Goldman	Massachusetts General Hospital
John	Goodenough	Software Engineering Inst.
Deniz	Gurkan	University of Houston
Rick	Hampton	Partners HealthCare System
Bryce	Hayashida	Karl Storz Endoscopy America, Inc.
John	Hayes	University of Michigan
John	Hedley-Whyte	Harvard University
Dyke	Hendrickson	CIMIT
Glenn	Himes	The Mitre Corporation
David	Hislop	

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Raoul	Jetley	FDA
Paul	Jones	FDA
Tom	Judd	Kaiser Permanente
Peter	Kazanzides	Johns Hopkins University
Arif	Khan	Southcoast Hospitals Group
Ji Eun	Kim	University of Pittsburgh
Frankie	King	NCO NITRD
Robert	Kolodner	Dept of Health & Human Services
Kai	Kuck	Draegerwerk AG
Philip	Kuryloski	Cornell University
Ben	Kwan	Polytechnic University
John	LaCourse	University of New Hampshire
Patrick	Lafleche	Stryker Medical
Brian	Larson	Boston Scientific
Insup	Lee	University of Pennsylvania
Kathy	Lesh	The MITRE Corporation
Jane	Liu	Academia Sinica
Steve	Liu	Texas A&M University
Manfred	Maiers	ACIST Medical Systems
Don	Malackowski	Stryker
Rahul	Mangharam	Carnegie Mellon University
Sowmya	Manjanatha	Boston University
Harry	Manolopoulos	MiSim
Ronald	Marchessault	TATRC
Amen Ra	Mashariki	Morgan State University
Tammara	Massey	UCLA
Martha	Matzke	NCO NITRD
Robert	McCready	The MITRE Corporation
Jay	McGuire	Cardiopulmonary Corp.
Paul	McKneely	MediCAN Systems, Inc.
Matthew	Meitzner	ECRI Institute
Yitzhak	Mendelson	Worcester Polytechnic Institute
Joerg-Uwe	Meyer	Draegerwerk AG
Scott	Midkiff	NSF
Debra	Milamed	Harvard Medical School
Austin	Montgomery	Software Engineering Institute
In	Mun	HCA
Ronald	Newbower	CIMIT
Jeff	Ojala	University of New Hampshire
Andrea	O'Neill	ZOLL Medical
Jason	Padvorac	University of Washington
John	Parrish	CIMIT
Frederick	Pearce	Walter Reed Army Institute of Research
Joshua	Pearl	IXXAT, Inc.
Tomasz	Petelenz	Sarcos Research Corp & University of Utah

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James	Philip	Brigham & Women's Hospital
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Steven	Rakitin	Software Quality Consulting
Tracy	Rausch	DocBox Inc
Elaine	Richardson	CIMIT
David	Ristau	Northern Digital Inc.
Jeff	Robbins	LiveData, Inc.
Michael	Robkin	Kaiser Permanente
Kurt	Rohloff	BBN Technologies
Carol	Rozwell	Gartner
Harvey	Rubin	University of Pennsylvania
John	Rushby	SRI International
Majid	Sarrafzadeh	UCLA
Vish	Sankaran	Office of the National Coordinator for Health IT
Rick	Schrenker	Massachusetts General Hospital
Thilo	Schumann	CAN in Automation
Jeff	Scott	LiveData, Inc.
Brent	Seales	University of Kentucky
Lui	Sha	University of Illinois
Chi-Sheng	Shih	National Taiwan University
Nat	Sims	Massachusetts General Hospital
Frank	Sites	Hospital of the University of Pennsylvania
Oleg	Sokolsky	University of Pennsylvania
Bill	Spees	FDA
Sylvia	Spengler	NSF
Soundararajan	Srinivasan	Robert Bosch LLC
Mani	Srivastava	UCLA
Binay	Sugla	Mobile Matrix, Polytechnic Univ
Mu	Sun	University of Illinois at Urbana-Champaign
Thomas	Szabo	Boston University
Carl F.	Wallroth	Draeger Medical, Inc.
Jonathan	Waters	University of New Hampshire
Sandy	Weininger	US FDA
James	Welch	Masimo
Susan	Whitehead	CIMIT
David	Whitlinger	Intel / Continua Health Alliance
Karl	Wolf	McKesson Provider Technologies
Han-Chun	Yeh	Academia Sinica
Raymond	Zambuto	IHE-USA
Warren	Zapol	Massachusetts General Hospital
Zachary	Zimmerman	Kaiser Permanente

145 attendees

June 2007 Joint Workshop on HCMDSS and MD PnP
Attendees by Organization / Company

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ALZA	Amy	Droitcour
BBN Technologies	Kurt	Rohloff
Boston Scientific	Brian	Larson
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	Mark	Gaynor
	Sowmya	Manjanatha
	Thomas	Szabo
Brigham & Women's Hospital	Jennifer	Jackson
	James	Philip
CAN in Automation	Thilo	Schumann
CapsuleTech, Inc.	Ann	Demaree
Cardiopulmonary Corp.	Jim	Biondi
	Jay	McGuire
Carnegie Mellon University	Orieta	Celiku
	David	Garlan
	Rahul	Mangharam
	Raj	Rajkumar
CIMIT	Steven	Boutrus
	Janice	Crosby
	Penny	Ford-Carleton
	Dyke	Hendrickson
	Ronald	Newbower
	John	Parrish
	Elaine	Richardson
	Susan	Whitehead
Cornell University	Philip	Kuryloski
Datascope Corp	Scott	Eaton
	Jim	Fidacaro
Dept of Health & Human Services	Robert	Kolodner
DocBox Inc	Gordon	Fowler
	Tracy	Rausch
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Draegerwerk AG	Kai	Kuck
	Joerg-Uwe	Meyer
ECRI Institute	Matthew	Meitzner
FDA	Raoul	Jetley
	Paul	Jones
	Bill	Spees
	Sandy	Weininger
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Fremont Associates	Duncan	Clarke
Gartner	Carol	Rozwell
Georgetown University	Mary Lou	Ingeholm
Harvard Medical School	Debra	Milamed
Harvard University	John	Hedley-Whyte

HCA	In	Mun
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Hospital of the University of Pennsylvania	Frank	Sites
IHE-USA	Raymond	Zambuto
Intel / Continua Health Alliance	David	Whitlinger
IXXAT, Inc.	Joshua	Pearl
Johns Hopkins University	Jim	Fackler
	Peter	Kazanzides
Kaiser Permanente	Tom	Judd
	Michael	Robkin
	Zachary	Zimmerman
Karl Storz Endoscopy America, Inc.	Bryce	Hayashida
LiveData, Inc.	Jeff	Robbins
	Jeff	Scott
Masimo	James	Welch
Massachusetts General Hospital	Julian	Goldman
	Rick	Schrenker
	Nat	Sims
	Warren	Zapol
McKesson Provider Technologies	Karl	Wolf
McMaster University	Marwan	Abdeen
Medical Connectivity	Tim	Gee
MediCAN Systems, Inc.	Paul	McKneely
MiSim	Harry	Manolopoulos
MIT	David	Broniatowski
Mobile Matrix, Polytechnic University	Binay	Sugla
Morgan State University	Amen Ra	Mashariki
National Taiwan University	Chi-Sheng	Shih
NCO NITRD	Trudy	Bell
	Sally	Howe
	Frankie	King
	Martha	Matzke
NIBIB/NIH	Zohara	Cohen
NIST	John	Garguilo
Northern Digital Inc.	David	Ristau
NSF	Scott	Midkiff
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Philips	Javier	Espina
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Polytechnic University	Ben	Kwan
Robert Bosch	Soundararajan	Srinivasan
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	Tammara	Massey
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University of Illinois at Urbana-Champaign	Lui	Sha
	Jennifer	Hou
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University of Michigan	John	Hayes
University of Modena and Reggio Emilia	Francesco	De Mola
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University of Pennsylvania	David	Arney
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	Oleg	Sokolsky
University of Pittsburgh	Ji Eun	Kim
University of Washington	Yung-Chun	Chen
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University of Western Ontario	Steven	Dain
Walter Reed Army Institute of Research	Frederick	Pearce
Washington University, St. Louis	Christopher	Gill
Worcester Polytechnic Institute	Yitzhak	Mendelson
ZOLL Medical	Andrea	O'Neill
No current affiliation	David	Hislop

Interoperability is an important issue for FDA and CDRH because it presents the potential to improve patient safety and clinical efficiency, but it comes with some unique regulatory challenges. Part of CDRH's mission is to ***protect*** the health of the public by ensuring the safety and effectiveness of medical devices. How can we be assured that a system of interconnected medical devices — in a potentially unknown configuration and possibly from different manufacturers — performs safely and effectively? Who is responsible when the system fails? With clinical users demanding increased capability to configure these complex systems, where does one draw the line between systems engineering and the practice of medicine (for example, can a bedside physician install an arbitrary clinical protocol)? How will we review devices that claim interoperability with others as part of their intended use? What criteria will we use for such reviews?

CDRH has the tools to resolve the issues that will inevitably arise. Our principal tool is the medical device law, which embraces fundamental principles rather than prescriptive practices. Our regulatory tools are based on a systems engineering approach, focusing on how well a given system satisfies a medical intended use. This systems approach, which works well for complex systems provided by one manufacturer, can be extended to systems of interconnected devices from multiple manufacturers.

One indication we are interested in patient safety and interoperability is the Center's recent efforts to work toward a unique device identification system. There is no such system universally recognized and we see this as a hindrance to interoperability and also a hindrance to patient safety in many other ways. We are working toward such a system enforced by our regulatory process.

Another part of CDRH's mission is to ***promote*** the public health. Public health promotion means a lot of different things, but fundamentally, to us, it means being prepared to review innovative new medical products rapidly as well as thoroughly. This requires anticipating emerging technologies and developing an understanding of their clinical impact before they arrive on our doorstep. FDA has demonstrated a commitment to interoperability by hosting meetings and making resources available [committed personnel & OSEL has some projects in this area), supporting standards development]. Our efforts have been to improve our understanding of the background clinical requirements and underlying technologies to implement such systems. FDA has been proactive in trying to prepare for regulatory submissions by raising issues of safety early and often.

By participating with industry in standards development activities, we can facilitate interoperability and make sure safety gets discussed as a primary requirement early in the development process. By discussing our regulatory concerns with manufacturers during product development, the salient issues concerning safety and effectiveness can be addressed in the first submission, reducing the need for extra review cycles. By teaming with other Federal agencies and coordinating our efforts, we can create a road map to efficiently and safely develop a successful, open-source based interoperability framework.

So our role is not just to sit back and wait for the submissions to be submitted, but rather to actively engage with academia, industry, and clinicians in deciding how future medical device users might benefit from increased automation and information sharing. The CDRH staff who are here today participating in this meeting are one overt indication of our commitment. They are representing those of us who, for one reason or another, were not able to attend. You may be assured that there are a lot of us in CDRH who are vitally interested, on behalf of the American people, in the work you are doing.

Donna-Bea Tillman, Ph.D.
Director, Office of Device Evaluation
Center for Devices and Radiological Health

Larry Kessler, Sc.D.
Director, Office of Science and Engineering Laboratories
Center for Devices and Radiological Health

Chair, Global Harmonization Task Force

Proceedings

2007 Joint Workshop on High Confidence Medical Devices, Software, and Systems

and

Medical Device Plug-and-Play Interoperability

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Monday, June 25, 2007

Getting medical devices to talk to each other

By Elizabeth Cooney, Globe Correspondent

There is no shortage of examples to illustrate the frustrating technological gaps that can put patients' lives at risk, **Dr. Julian M. Goldman** told a conference on health care technology and safety yesterday.

Take the ventilator used during heart surgery, for instance, the Massachusetts General Hospital anesthesiologist and biomedical engineer said. The patient needs the ventilator both before and after using the heart/lung machine that pumps blood during heart surgery. But doctors can forget to turn the turn the ventilator back on – and the alarm that signals when the machine isn't working is often silenced because it tends to go off unnecessarily. It would make sense if there were an alarm that sounded only when both machines were off, but that's not possible, Goldman said, because the two machines, made by different companies, can't talk to each other.

"There's no shortage of clinical scenarios," Goldman, of Massachusetts General Hospital, said in an interview, after a morning filled with stories of fragmented health information. "The challenge is to turn war stories into actionable solutions."

Interoperability – the way for medical devices to work together – is the subject of the three-day conference that started in Cambridge today and is sponsored by the Center for Integration of Medicine and Innovative Technology among others. The conversation includes electronic health records in all settings and remote monitoring of health conditions.

Dr. Robert M. Kolodner, National Coordinator for Health Information Technology, challenged audience members from health care, business and government to forget their

COMMENTS? TIPS?

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UPCOMING EVENTS

- Events: June 25-30...
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Posted by Elizabeth Cooney at 03:08 PM

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BLOGGER

Elizabeth Cooney is a health reporter for the Worcester Telegram & Gazette.

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Patient Safety & QUALITY HEALTHCARE

By Susan Carr, Editor

Plug and Play for Patient Safety

Most of what I hear about interoperability refers to sharing data among information systems. But in late June, I spent 3 days at a joint conference of organizations working on the interoperability of medical devices. This kind of interoperability would include devices that automatically communicate with information systems; devices that could take information from another device and display or use it, for example, to issue a clinical alarm; and even medical devices that could perform clinical interventions based on information received from patient monitors or other devices.

Julian Goldman, MD, set the stage on the first day by describing the "high-level" goal of the conference: to empower healthcare providers with interoperable medical systems, similar to the way that consumers have been empowered by interoperable electronics such as cellphones, digital cameras, and PDAs. Goldman and other speakers emphasized that the solutions must be based on clinical need, not driven by the technology itself, must comply with widely accepted standards, and that the technology must be verified, validated, and certified.

"Improving Patient Safety through Medical Device Interoperability and High Confidence Software" was a collaboration of two communities: High Confidence Medical Devices, Software, and Systems (globally distributed computer scientists from academia and government, led by a group at the University of Pennsylvania School of Engineering & Applied Science), and the Medical Device Plug and Play (MD PnP) program at the Center for Integration of Medicine & Innovative Technology (www.CIMIT.org). The conference drew 141 attendees, including clinicians—especially anesthesiologists and intensivists—and engineers (software, clinical, and biomedical) as well as representatives from academia, industry, and government, with a good number of attendees and speakers from countries outside the United States.

Topics included clinical needs for device interoperability and prospective device solutions, software engineering concepts that are beyond me, forward-thinking concepts such as cyber-physical systems, and a mind-boggling array of acronyms. I was not alone in occasionally feeling lost. However, in this group of experts exchanging ideas across sophisticated professional languages, frequent references to the world of safety and quality improvement reminded everyone of our common purpose: improving patient care.

To learn more about the conference, see http://rtg.cis.upenn.edu/hcmdss07 and www.mdpnp.org, as well as Tim Gee's blog (www.medicalconnectivity.com). Tim reported on the conference daily and helped wrap it up with a "Report from the Blogosphere." Coincidentally, I am delighted to welcome Tim as the newest member of *PSQH's* Editorial Advisory Board. PSQH